RECEIVED
CENTRAL FAX CENTER
OCT 09 2008

BY FACSIMILE

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
11201-735-999	

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/797,565	March 11, 2004
First Named Inventor	
Steven M. Griffiths	
Art Unit	**Examiner**
3767	Elizabeth MacNeill

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record. Registration number 40,210

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

Garry J. Tuma
Typed or printed name

212-326-7845
Telephone number

October 9, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

BY FACSIMILE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

Applicant:	Steven M. Griffiths	Confirmation No.:	4820
Application No.:	10/797,565	Art Unit:	3767
Filed:	March 11, 2004	Examiner:	Elizabeth MacNeill
For:	NEEDLE AND HUB ASSEMBLY FOR AUTOMATIC INJECTOR	Attorney Docket:	11201-735-999

New York, New York 10017
October 9, 2008

Mail Stop AF
Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REMARKS FOR PRE-APPEAL BRIEF CONFERENCE

Sir:

Applicant requests review of all rejections in the July 9, 2008 final Office Action ("FOA"), because prima facie obviousness has not been established.

Claims at Issue

Independent claim 1 and dependent claims 2-7, 9, and 28 stand rejected under 35 U.S.C. § 103(a) as being obvious from Kruck U.S. Patent No. 3,974,832 (hereinafter "Kruck").

Independent claim 10 and dependent claims 11-16, 18-21, and 29 stand rejected under 35 U.S.C. § 103(a) as being obvious from Kruck in view of Sarnoff et al. U.S. Patent No. 4,755,169.

Rejections of Independent Claims 1 and 10 Under 35 U.S.C. § 103(a)

Applicant claims a needle and hub assembly for a drug delivery injection device (independent claim 1) and an automatic drug delivery injector having the elements of a needle

and hub assembly (independent claim 10). In particular, independent claims 1 and 10 each require, among other things, that a wall of a cap be adjoined on its exterior surface by a second hub portion and be adjoined on its interior surface directly opposite the adjoined exterior surface by a first hub portion so as to form a contiguous, mutually reinforcing sandwiched structure of the second hub portion, the wall, and the first hub portion.

An example of this structure is shown in applicant's FIGS. 2 and 4 where second hub portion 44, wall 50, and first hub portion 42 form a contiguous, mutually reinforcing sandwiched structure. This structure prevents the wall "from warping, distorting, or otherwise deforming due to the stresses encountered during automatic injection" (applicant's specification, page 9, lines 4-6).

As argued in applicant's May 19, 2008 Reply to Office Action on pages 11-12, Kruck's hypodermic needle assemblage does not meet this limitation. This is best shown in Kruck's FIG. 1, where hub shoulder 56 of hollow key member 48 (≈ the first hub portion) contacts internal shoulder 40 (≈ the wall) of ferrule 26 (≈ the cap) -- but flange 52 of cup portion 46 (≈ the second hub portion) does not contact ferrule 26 directly opposite internal shoulder 40 (≈ the wall) of ferrule 26 -- there is a gap between shoulder 40 (≈ the wall) and flange 52 (≈ the second hub portion). The same is true on the other side of the needle assemblage.

The Examiner said that "Kruck does not teach any reason for having a gap or why this gap is important to the function of his invention" (FOA, page 3).

Although Kruck did not explicitly disclose a reason for the gap, this does not prove that the gap is not important to the functioning of Kruck's needle assemblage. Indeed, applicant submits that the gap may play an important role in the "unique locking arrangement at

the forward end of the ferrule 26" (column 3, lines 30-31), which involves insertion and rotation of various interconnecting parts. For example, Kruck discloses that to lock cup portion 46 to ferrule 26, cup portion 46 is rotated on upper surface 58 of ferrule 26 to a locked position. Thus, the gap appears to play the important role of reducing surface friction so cup portion 46 can be more easily rotated on ferrule 26.

The Examiner then concluded that it would have been obvious "to flatten top 58 so that a sandwich is formed from 1st hub to wall 2nd hub to further reinforce the wall portion" (FOA, pages 3-4).

If the gap serves the purpose of reducing surface friction, then removing the gap may render Kruck's device unsatisfactory. If this is the case, then flattening top 58 is not an obvious modification.

Also, the Examiner cited no reference with such a structure or any other evidence to support the conclusion that such a modification is obvious.

Kruck's hypodermic needle assemblage is intended to be used with a hand operated hypodermic syringe (note the finger grips near the base of plunger 14 in FIG. 1). Accordingly, Kruck's device is not subjected to the high stresses typically generated by automatic injectors.

Thus, there is no reason why a person of ordinary skill in the art would be motivated to "further reinforce" that wall portion.

Moreover, even if a person of ordinary skill were motivated to further reinforce that wall portion, the Examiner cited no evidence to support the assertion that "flattening top 58" would be an obvious modification -- applicant submits that there are other ways to "reinforce the

wall portion" that may be much more likely to be made, such as, for example, increasing the thickness of the wall.

Accordingly, applicant respectfully submits that the Examiner is using applicant's own teachings, that is, impermissible hindsight, to conclude that "flattening top 58" would be obvious.

The Examiner further said that "'sandwiching' is obvious for two reasons: first, the examiner believes this may be already shown because of the slanted slots in the wall 58, and because one of ordinary skill in the art could easily modify the device to remove the gap" (FOA, page 6).

First, the Examiner's belief is not clearly supported. Kruck's FIG. 1 is the only view that shows the relationships between the three structures when the device is in "the locked or needle-retaining position" (column 2, lines 26-27). The gaps between cup portion 46 (≈ the second hub portion) and internal shoulders 38 and 40 (≈ the wall) clearly exist.

Second, the mere fact that a modification can be easily made does not render the modification obvious unless it would have been predictable (see MPEP §2143.01 (III)).

And the Examiner cited no evidence to show that flattening top 58 is a predictable modification, particularly in view of the gap's apparent importance and other modifications that could be made instead.

Rejections of Dependent Claims 28 and 29 Under 35 U.S.C. § 103(a)

Dependent claims 28 and 29 each require the needle-receiving channel to have a stop formed therein to limit the insertion depth of the needle within the first hub portion. An example of this limitation is shown in applicant's FIG. 4, where stop 58a limits the insertion of needle 46 within first hub portion 42.

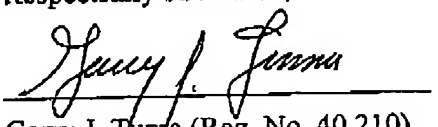
The Examiner said that Kruck's hollow key member 48 (≈ the first hub portion) "has two stops -- [hub] shoulder 56 and its distal most end -- which abut the wall and 2nd hub [i.e., cup portion 46]." The Examiner continued, "The 2nd hub holds the needle and abuts the end of the first hub," and concluded that "the distal most end of the 1st hub has stop which limits the insertion depth of the needle within the first hub portion." FOA, page 4.

As shown in Kruck's FIG. 1, there is no stop in the needle receiving channel that limits the insertion depth of needle 24 within hollow key member 48 (≈ the first hub portion), or any other structure for that matter, as needle 24 is plainly shown extending completely through the first hub portion and into syringe barrel 12 -- the insertion depth appears to be limited by only the length of the needle itself and/or the length of the syringe barrel and other parts of Kruck's needle assemblage.

Conclusion

Applicant respectfully submits that the Examiner has not met the burden of establishing a prima facie case of obviousness.

Respectfully submitted,



Garry J. Tuma (Reg. No. 40,210)
Attorney for Applicant

JONES DAY
Customer No. 20583
222 East 41st Street
New York, New York 10017
(212) 326-3939